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(61) Addition to: P 39 35 818.6

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(54) Wound-cleansing and -treating Device

(57) Wound-cleansing and -treating device for cleansing contaminated wounds in daily practice. The technical object is to locally treat decubital ulcers and ulcus cruris, i.e., ulcer of the lower leg and bedsore, at the bedside and in daily practice.

The problem is solved by cleansing the wound by means of two separate pressure and drainage pumps and a cuff, which can be fastened to the organ by means of a rubber band, by applying water by means of the pressure nozzle located in the cuff, while the irrigating fluid is drawn off at the same time by the drain nozzle located, e.g., at the bottom of the cuff. Cleansing and therapeutic substances may be added to the solution. By application at the bedside, it is possible to avoid the often difficult transfer of the patient into the bathroom, etc. Another type of application, which the patient likes to use, is the treatment of local processes, especially in the area of the limbs, e.g., rheumatic swellings, etc.; soluble antirheumatics are added to the fluid in this case and applied directly to the diseased organ under pressure. The fields of application are consequently the cleansing of all types of ulcers and the local treatment of pathological swellings. Further thorough investigations are needed to determine whether renal clearance can take place via the skin and with pressure suits.

Specification

Concerning a patent of addition to P 39 35 818.6, I would like to subsequently assert the following features: The Aquaderm wound-cleansing and -treating device requires two pump units with separate circuits. The drawing for this was sent to you previously. The operating instructions shall also be part of the patent of addition. The cuff mechanism shall be protected, in particular; the spray and nozzle heads are part of the overall system; they may have multiple nozzles, a single nozzle, and other features, and the pressure gradients, such as the pulse pressure gradients, the fine adjustment, and the massive increase in pressure up to tissue infiltration, may vary as well. The variability of the drainage mechanisms shall be protected as well; thus, it is possible to use various materials, and even double-walled cuffs are possible. The drain nozzle has multiple possible variations. The various possibilities shall be protected here by the patent. In particular, the entirety of the device, which consists of many individual components, is to be subjected to the patent regulations. Furthermore, a pressure gauge is installed; its range is about 0-3 bar or more. A temperature sensor for measuring the fluid is also possible, and a short-time watch shall also be installed to control the duration of the application. These material contents shall also be protected by the patent within the entire function of the device unit. No control mechanisms of the computer class are intended to date, but if these will be needed later, they should also be patented as they are useful for the function of the device.

The ring-shaped, double-walled drainage and cleansing cuff would have the advantage that the tightening bands would be omitted and the cuff would automatically adhere to the skin surface under vacuum; a drawing is enclosed for demonstration. An additional vacuum pump, which would be based on air, should also be installed in the device for this purpose. Many different variations are available here, and they should also be protected by the patent.

Regarding the cuff heads to be developed, they are not ready, but they will be produced soon. Different fitting forms are to be developed for the individual limbs, but the general principle of irrigation and drainage in the skin area is preserved. Rectal and vaginal pressure and drainage heads are also to be developed and protected by the patent. A kind of tissue cutting can also be performed by designing the cuff heads as transparent cuff heads and by correspondingly increasing the pressure jet, but even more powerful pressure units are needed for this purpose, which shall be developed. A glass window-like insert is also conceivable for performing the local removal of necrotic wound components (so-called wound excision) by viewing on or through the cuff. On the whole, it would be important to patent the closed circulation system with the application of the cuff and the pressure or drain nozzle, as well as the other implements described.

Operating Instructions for Aquaderm

Table of Contents

1.1.1. Setup

Place the device vertically or horizontally on the rubber pad provided for this purpose.

1.1.2. Connection

a) Plug the device into the 220 V/50 Hz power supply system.
b) Connect the thick tubes to the inlet and outlet on the side and plug the ends into the containers provided for this purpose.
c) Connect the cuff and the device to the thin tube and the adapter tubes, making sure that the left-hand connection is the feed tube, which leads to the top side of the cuff.

1.1.3. Switching On

The device may now be switched on at any time. It is important to ascertain in advance that the adjusting stopcock is closed (right stop).

During use, open slowly until the desired pressure is reached. The best action is obtained after only half a turn.

1.1.4. Application of the Cuff

When applying the cuff, it must be ensured that the cuff is not compressed in itself and the drain is located at the lowermost point.

The patient may hold the cuff himself, under a gentle pressure. As an alternative, you may also use the tightening bands supplied.

1.1.5. Scientific Application

For the duration and the handling of wound treatments, refer to the accompanying scientific instructions.

2.1.6. Cleaning and Disinfection of the Cuff

After use, pull off the cuff tubes on the cuff side and place them into a disinfecting solution.

Now attach the second cuff to the tubes and continue the treatment.

2.1.7. Cleaning and Disinfection of the Device

If two containers are used all the time, disinfection of the system does not need to be performed. Nevertheless, it is advisable to rinse the system once a week. To do so, use a vinegar solution or a disinfecting solution. Connect the cuff tubes and use the cleaning container in continuous circulation.

2.1.8. After Use

To remove the residual fluid, pull the drain tube out of the container after use and wait until only a small amount of residual fluid flows out of the tube system.

3.1.9. Problems

a) If the tubes are no longer sufficiently tight, cut off a piece and pull the tubes on again.
b) If the drain from the cuff no longer functions, clean the drain nozzle. To prevent a further flood of water, first check without cuff by connecting the cuff tubes.
c) If a leak develops, the fluid can flow out of the device through 2 water separators in the bottom of the device or in the bottom plate. Notify your supplier in this case, or open the device by removing the 8 screws from the cover, and look for the leak. You may repair minor leaks yourself.

4.1.1. Important Notes

In the case of application with drugs in continuous circulation, the device should be rinsed with a disinfecting solution to achieve the best hygienic conditions.

The device should be checked for possible leaks by visual inspection once or twice a year.

Always make sure to turn the regulator to the right stop before switching on the device.

The regulator must be closed before removing the cuff after a treatment to make it possible to drain off the residual water from the cuff.

5.1.1. Checklist for Daily Wound Cleansing

1. Connect to power supply.
2. Connect inlet/drain to the thick silicone tube.
3. Connect cuff and thin tubes and connect to device via adapters. Check tube for correct seating in container.
4. Check if regulator is at the right stop.

5. Switch device on.
6. Apply cuff.
7. Open regulator by about 1/2 revolution.
8. Replace cuff after treatment.
9. Disinfect used cuff.
10. Remove fluids.
11. Rinse and empty device or
12. Briefly rinse device with disinfecting solution and empty it.

Technical Specifications

a) Power supply
Power consumption 80 W
Voltage 220 V/50 Hz
Pump voltage 12 V/3 A

b) Pump output
Pressure regulation via valve relay

c) Principle
1 pump unit for suction
1 pump unit for drainage
Controlled with regulator.

Description of the Medical Indications of the AQUADERM Wound-Cleansing Device

Problem-free cleansing of the base of the wound can be performed by means of the attachable cuff and the cleansing nozzle in ulcerous processes in the skin area, which are usually superinfected with pathogenic microorganisms (*Staphylococci, Streptococci*). Wound cleansing is a prerequisite for the wound-healing process in hospitals in the case of crural ulcer (decubital ulcers, decubital sepsis, etc.).

The wound granulations are to be removed before the application of the cleansing cuff; this is done best by means of a pair of forceps, after which the disinfecting and cleansing aqueous solution is applied. The process may be performed safely several times a week until the healing of the ulcer.

The edge of the wound is to be coated with a wound care ointment, after which it is to be covered under sterile conditions.

Due to edemas, varices, etc., oxygen supply is poorer in the area of the lower leg as a consequence of stasis, and the skin area damaged as a result is increasingly susceptible to infectious processes and ulcerations. A very high level of hygiene is therefore necessary in this area, scratching effects and small rhagades are to be avoided, in particular, and penicillins in the soluble form and other drugs may also be added to the irrigating solution. Another field of indication for water therapy is rheumatic swellings in the area of large joints. A change can be brought about here only by the specific use of warming water, and the good result can be potentiated by the addition of

corticosteroids, salicylates, antirheumatics (in the form of solutions or soluble tablets).

However, no ascertained data are available on this as yet. Degenerative processes as well as punctiform periosteal irritations, such as periostitis and epicondylitis, etc., are another field of indication. The process can be favorably influenced therapeutically here by increasing the pressure jet.

The combination of Aquaderm and an electrostimulating device, similarly to a hydroelectric bath, but in a small format, shall be patented as well. An electrode, which may also be bipolar, i.e., in the multiple form, and which introduces stimulating currents into water, is arranged in the cuff in a suitable manner for the prior-art water therapy.

State of the Art with References

1. Venous ulcers of the legs have been known to be very common; it is estimated that one percent of the population is affected by this condition (*Ärztliche Praxis*, No. 85 of October 23, 1990). This condition is often resistant to therapy. This also applies to decubital ulcer, i.e., bedsore; its treatment is difficult; the base of the wound is cleansed by applying ointments and compresses impregnated with Ringer's solution (*Ärztliche Praxis*, No. 65 of August 14, 1990). It is also known that the legislator has imposed very strict requirements on the treatment of bedsore, because this condition may frequently cause death.

2. Object: The underlying object of the invention described in patent claim 1 is to eliminate bacterially contaminated wounds, which present themselves as greasy films in order to thus achieve optimal healing.

3. This object is accomplished by the features described in patent claim 1.

4. The advantages achieved with the present invention are especially that the greasy substrate is cleaned by a few applications of the device, as a result of which the ulcer is healed, instead of a plurality of applications of an ointment and other dressings, which may even exacerbate the condition. Bedridden patients no longer need to be brought to the bathroom, which is difficult, to cleanse the wounds. Such advantages were achieved in practical trials.

5. One advantageous embodiment of the present invention is described in patent claim 2, in which the size of the rubber bells may be variable. This system makes it possible in a simple manner to add various substances for the therapy by adding them to the irrigating fluid. Inflammatory changes, such as those occurring in the case of, e.g., joint rheumatism, can also be made accessible to a causal therapy due to this arrangement by intracutaneously administering drugs under pressure.

Patent Claims

1. Wound-cleansing and -treating device for application in medical practice and hospitals, wherein a closed, moist chamber is formed by a rubber cuff, also called a rubber bell, which can be placed over the wound. The base of the ulcer is cleansed by means of an irrigating nozzle, which is fastened in the upper part of the rubber bell; another drain nozzle in the lower area of the bell ensures the removal of the irrigating fluid. Two pumps operating independently from one another ensure the continuous circulation. The irrigating fluid is drawn in from one container, and the fluid drawn off, which is now contaminated, is introduced into another container or into the same container.

2. The rubber cuff in accordance with claim 1 may have various fitting shapes. The rubber cuff is fixed by means of a rubber band, which has perforated openings.

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2 pages of drawings attached

DRAWINGS PAGE 1 No.: **DE 41 11 122 A1**
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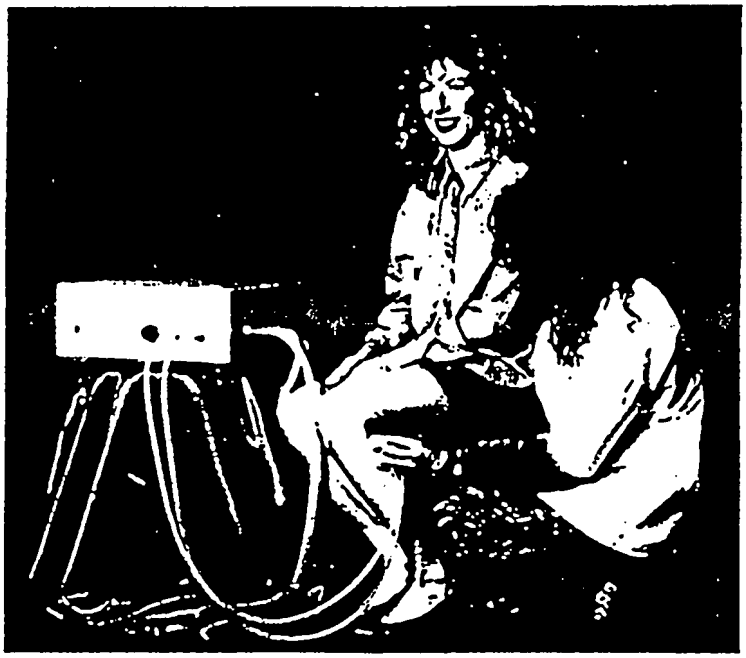
SPECIFICATION HP 60 L

Figure 1



Indications Tested to Date:

Crural ulcer
Decubital ulcers
Poorly healing wounds with lymphangitic phenomena
Water therapy in myalgias, degenerative processes, rheumatic swellings

Possible Therapeutic Applications

Care for the elderly
Surgery
Clinical care
Treatment by natural remedies
Orthopedics [difficult to read - Tr.Ed.]

Applications

Problem-free application at the bedside
In the outpatient medical office

Connection to the plumbing is not necessary due to closed water circulation.

Technical Specifications

Power consumption	80 W
Power requirements	220 V · 5
Pump voltage	12 V · 3
Safety	VDE
Dimensions	40 x 35 x 16
Weight	approx. 10 kg

Standard Equipment

Device (without cart)
4 tubes
Cuffs

Options

Cart
Tubes
Cuffs

DRAWINGS PAGE 2

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1 = Pressure and drainage pump
2 = Pressure and drainage pump
3 = Cleansing cuff with irrigating and drain nozzles
4 = Base of wound
5 = Container for cleansing fluid

Figure 2